Remarks

The Office Action mailed March 11, 2005 has been received and reviewed. The pending claims are claims 1-24, 48, 100-110. Reconsideration and withdrawal of the rejections are respectfully requested.

Finality of Office Action

Although the Office Action Summary indicates this action is final, it is indicated as a nonfinal action in PAIR. Also, a telephone call to the Examiner's Supervisory Patent Examiner, Long V. Le, confirmed that this action is not final due to the presence of new art and new rejections. Confirmation of this is requested.

The 35 U.S.C. §112, Second Paragraph, Rejection

The Examiner rejected claims 1-24, 48, and 100-101 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner has objected to the language "nonporous latex-derived" material. This rejection is respectfully traversed. A latex is a well-known term. Furthermore, Applicants have clearly explained that a latex includes polymer particles in water (e.g., at page 11, lines 22-25 of the specification, Applicants explain that "each polymer used is preferably derived from a latex (e.g., water delivered polymer particles), whether it be naturally occurring or synthetic."). Applicants also list a number of examples of such materials at page 11, line 22 through page 12, line 6. Thus, the claims recite a polymeric material that is nonporous and derived from a latex polymer, which one of skill in the art would fully understand.

The 35 U.S.C. §103 Rejections

The Examiner rejected claims 1-13, 15-24, 48, 100-104, 106-108, and 110 under 35 U.S.C. §103(a) as unpatentable over Thiagarajan et al. (*European Federation of Biotechnology*,

1995; pgs. 304-312) in view of Foster et al. (U.S. Patent No. 4,444,879). This rejection is respectfully traversed.

Thiagarajan et al. teach a thin film plug reactor (TFPR) that can be used to study the physiology of *E. coli* that are permanently immobilized in thin films made from a latex copolymer of acrylic and vinyl acetate (pages 304 and 306). The TFPR consists of a glass chamber that contains an aluminum plug whose surface is coated with a mixture of copolymer and *E. coli* cell paste using a drawdown method (page 305). An alternative method uses cell + polymer-coated pressure sensitive polyester attached to the aluminum plug (page 305).

The plug reactor was described as being a model system for designing porous immobilization media and bacterial cells to sustain biocatalytic activity for long periods of time (page 312). The films used within a TFPR are described as exhibiting diffusion properties that are related to polymer particle coalescence and film structure, which further indicates the porous nature of the films, as diffusion would not occur through a nonporous film. Thiagarajan et al. used the TFPR to study oxygen uptake from medium that was in contact with the film of the TRPR.

Claims 1, 2, 11, 12, 18, 22, 109 and 110 are directed to a composite biological device comprising a biostructure comprising at least one biological material that is metabolically active or becomes metabolically active upon hydration . . . wherein at least a portion of the biostructure comprises a nonporous latex-derived material. Claims 48, 100-105 and 107-108 are directed to a method of determining the presence of an analyte in a sample . . . upon contact with the analyte, wherein the biological material, which is metabolically active or becomes metabolically active upon hydration, produces a response and emits a signal; and detecting the signal. Furthermore, the methods include use of a device that comprises a nonporous latex-derived material and biological material is metabolically active or becomes metabolically active upon hydration.

As admitted by the Examiner at page 3 of the Office Action, Thiagarajan et al. do not teach a device that includes a nonporous latex-derived material (claims 1, 2, 11, 12, 18, 22, 109 and 110). The Examiner cited Foster et al. for teaching a nonporous styrene latex. However, Foster et al. teach an antigen-antibody binding assay apparatus that includes a polymeric resin

having attached chemical groups capable of forming covalent bonds with immunoreactants (Abstract). There is no teaching or suggestion that the polymeric resin of Foster et al. could be combined with the device of Thiagarajan et al. to obtained Applicants' invention. In fact, Foster et al. teach away from Applicants' invention.

Each of Applicants' independent claims recites that the biological material is metabolically active or becomes metabolically active upon hydration. The immunoreactants of Foster et al. are not metabolically active, nor do they become metabolically active upon hydration. Furthermore, if metabolically active biological material were covalently bonded to a polymer, it would no longer be metabolically active or capable of becoming metabolically active upon hydration. Thus, one of skill in the art would not combine the resin of Foster et al. (having chemical groups capable of forming covalent bonds) to the biological material of Thiagarajan et al.

In addition, neither Thiagarajan et al. nor Foster et al. teach a method to determine the presence of an analyte, or a method wherein a biological material produces a response and emits a signal upon contact with an analyte (claims 48, 100-105 and 107-108).

With respect to claims 1-4 and 110, it is respectfully submitted that Thiagarajan et al. do not teach or suggest that using printing methods selected from gravure coating, piezo-electric printing, and acoustic printing, can provide biostructures wherein the biomaterial, which is an integral part thereof, remains viable over extended periods of time and shows activity when used in assays. For certain embodiments (e.g., claim 110), the devices include three-dimensional (3-D) biostructures. Such 3-D microstructures can be built up in the form of an assembly comprising a large number of three-dimensional micro-wells, if desired, comparable to an extremely small microtiter plate. It was not recognized, prior to Applicants' invention, that such results could be achieved using these printing methods.

Therefore, Applicants respectfully submit that the combination of Thiagarajan et al. and Foster et al. do not render Applicants' claims obvious. Reconsideration and withdrawal of the rejection of the claims under 35 U.S.C. § 103(a) are respectfully requested.

The Examiner rejected claims 14 and 105 under 35 U.S.C. §103(a) as being unpatentable over Thiagarajan et al. in view of Foster et al. (U.S. Patent No. 4,444,879) and further in view of Cantwell et al. (EP 0 288 203). This rejection is respectfully traversed.

As discussed above, the combination of Thiagarajan et al. and Foster et al. would not provide Applicants' invention, which recites that the biological material is metabolically active or becomes metabolically active upon hydration, at least because if metabolically active biological material were covalently bonded to a polymer, it would no longer be metabolically active or capable of becoming metabolically active upon hydration. Cantwell et al. do not provide that which is missing from the combination of Thiagarajan et al. and Foster et al.

Cantwell et al. teach immobilized cells in which bacterial or fungal cells are immobilized in intimate admixture with a solid organic polymer, and to processes for the preparation and use thereof (page 2, lines 3-5). The structure and permeability to aqueous media of the compositions "is such that a substrate is allowed access to the cells containing the enzyme to which it is to be subjected; a composition allowing suitable water permeability is used, e.g. acrylates are often preferred to polyvinylidene chloride (which tends to be a barrier to H_2O)" (page 4, lines 47-50). Cantwell et al. further emphasize the preparation of porous compositions that allow a substrate to come into contact with a cell and thereby teaches away from composite devices that include nonporous components (although porous components can also be a part of Applicants' claimed composite device). Accordingly, it is respectfully requested that this rejection be withdrawn.

The Examiner rejected claim 109 under 35 U.S.C. §103(a) as being unpatentable over Thiagarajan et al. in view of Foster et al. (U.S. Patent No. 4,444,879) and further in view of Martens et al. (*Analytica Chimical Acta*, 1994; vol. 292; pgs. 49-63). This rejection is respectfully traversed.

As discussed above, the combination of Thiagarajan et al. and Foster et al. would not provide Applicants' invention, which recites that the biological material is metabolically active or becomes metabolically active upon hydration, at least because if metabolically active biological material were covalently bonded to a polymer, it would no longer be metabolically

active or capable of becoming metabolically active upon hydration. Martens et al. do not provide that which is missing from the combination of Thiagarajan et al. and Foster et al. Accordingly, it is respectfully requested that this rejection be withdrawn.

Summary

It is respectfully submitted that the pending claims 1-4, 11, 12, 14, 16, 18, 22, 109, and 110 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives at the below-listed telephone number if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for
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CERTIFICATE UNDER 37 CFR §1.8:
The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Commissioner for Patents, Mail Stop Amendment, P.O. Box 1450, Alexandria, VA 22313-1450, on this 13th day of June, 2005, at 11:40 a.m. (Central Time).

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